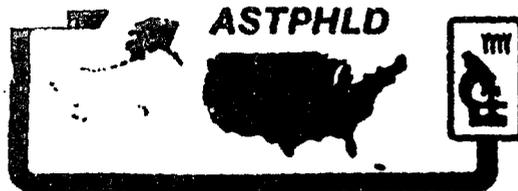


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James R. Cull 10/6/94
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T **TESTING**

Reno, Nevada
March 1994

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CONFERENCE SUMMARY

The Ninth Annual Conference on Human Retrovirus Testing, held in Reno, Nevada on March 2-4, 1994 advertised the following purpose. "A forum on national and international laboratory-related retroviral issues which will allow for an exchange of information and ideas and encourage discussion of current issues". Judging from the presentations delivered during the plenary sessions and issues forums and the discussions they evoked both in the sessions, at the evening breakouts and in the halls, the purpose of the conference was met.

The conference was sponsored by the Association of State and Territorial Public Health Laboratory Directors. As in previous conferences, the Ninth Conference addressed many of the issues associated with retrovirus testing and again served as a vehicle for the disseminations of attendees' concepts and views germane to human retrovirus testing. Over three hundred participants attended the three day conference. Fifty poster sessions were presented and 14 exhibitors presented products related to HIV testing.

Mr. Charles Schable, Chief of the Serology Section, CDC, presented a well attended session on "The Basics of Retroviral Testing: the evening before the main conference program. The session gave participants an opportunity to brush up on their knowledge of retroviral testing and set the stage for the conference program over the next two days.

The first plenary session addressed the status of human retrovirus testing and covered pediatric AIDS, alternative CD4 technologies, current issues of HTLV testing and an international perspective on HIV testing. AIDS is of global concern and the international perspective on HIV testing presented by Dr. Ofelia Monzon was enlightening.

The issues forum on Wednesday continued the on going discussion of algorithms. This conference report contains a summary of the discussion and conclusions reached. On Thursday non-traditional HIV testing was the subject of Issues Forum II. Non-traditional testing continues to be controversial with the introduction of home testing. Regulatory affairs were covered in the Wednesday afternoon issues forum. Discussion on regulatory issues have a way of evoking strong opinions and this meeting was no exception. The fourth issues forum was on Western Blot False Positive and Issues of Testing in the Era of Vaccines. West blot false interpretation and the problems associated with the testing methodology continue to be a challenge. The forum attempted to address the problems associated with this testing and the problems that vaccines are presenting. A position paper derived from the session is included in this report.

The conference was concluded by the second plenary session. The session addressed systemic lymphoid response in early HIV infection, new horizons in molecular testing of HIV and a report on ASTPHLD's international training efforts.

PLEASE NOTE:

This conference did not address issues previously address in the first eight Conferences on Human Retrovirus Testing. Proceedings from those conferences may be obtained from: ASTPHLD, 1211 Connecticut Avenue, N.W., Suite 608, Washington, D.C. 20036

PLENARY SESSION SPEAKERS

Pediatric AIDS: correlates of Perinatal Transmission and Strategies for Interruption
Diane Wara, M.D.

Alternative CD₄ Technologies
Janet Nicholson, Ph.D.

The HTLVs: Current Issues
Jonathan Kaplan, Ph.D.

HIV Testing - An International Perspective
Ofelia Monzón, M.D.

Systemic Lymphoid Response in early HIV Infection
Ronald Turnicky, D.O., LTC, MC

New Horizons in Molecular Diagnostics
Helen Lee, Ph.D.

ASTPHLD International Training
David Carpenter, Ph.D.

ISSUES FORUM: TESTING: HIV-1 AND HIV-2 ALGORITHMS

PANEL MODERATOR:

Jane Getchell, Dr.P.H., Associate Director, State Hygienic Laboratory, University of Iowa, Iowa City, Iowa

PANEL MEMBERS:

Barbara Werner, Ph.D., Director, Virology / Clinical Investigation Division, Massachusetts State Laboratory Institute, Jamaica Plain, Massachusetts

Robert Myers, Ph.D., Laboratory Scientist, Maryland Department of Health, Baltimore, Maryland

William Schalla, M.S., Chief, Model Performance Evaluation Program, Centers for Disease Control and Prevention, Atlanta, Georgia

Charles Schabel, M.S., Chief, Serology Section, Division of HIV/AIDS, Centers for Disease Control and Prevention, Atlanta, Georgia

Hermann A.M. Mücke, Ph.D., Senior Vice President of Research and Development, Waldheim Pharmazeutika R&D Laboratory, Austria

In the U.S. all HIV testing algorithms consist of a screening test followed by a confirmatory test. Beyond this, no single sequence of testing is common to all laboratories. The specific algorithm used depends on the prevalence of infection in the population, the resources available to the laboratory, the volume of testing, the desired turnaround time, etc. IFA and WB are acceptable confirmatory tests. For any first time positive report on an individual, a request should be made to submit another sample for repeat testing. Tests used in resolving inconclusive confirmatory test results include antigen assays, recombinant and synthetic based assays, and PCR.

Testing for HIV-2 as part of the screening process results in a greater number of specimens requiring supplemental testing, few of which are actually confirmed as HIV-2. Screening for HIV-1 alone detects 60 to 90% of HIV-2 infections. As of March 1994, 49 cases of HIV-2 infection have been reported in the U.S. from 13 states. States that have tested specimens giving atypical HIV-1 WB patterns (gag and pol bands only) with HIV-2 specific assays have successfully identified HIV-2 infection.

ISSUES FORUM NON-TRADITIONAL TESTING

PANEL MODERATOR:

Charles Schable, M.S., Chief, Serology Section, Division of HIV/Aids, Centers for Disease Control and Prevention, Atlanta, Georgia

PANEL MEMBERS:

J. Richard George, Ph.D., Chief, Developmental Technology Division, Division of HIV/AIDS, Centers for Disease Control and Prevention, Atlanta, Georgia

Ms. Cynthia Cossen, Supervising Microbiologist, VRDL, CA Dept. of Health, Berkeley, CA

William Kassler, Ph.D., National Center for Prevention Services, Centers for Disease Control and Prevention, Atlanta, Georgia

Wanda Jones, Dr. P.H., Assistant Director for Science, Office of HIV/AIDS, Centers for Disease Control and Prevention, Atlanta, Georgia

The use of non-traditional specimens such as dried blood spots or saliva have been shown to be technically feasible. Research assays using EIA or WB specifically designed for, or modified for such specimens are clearly concordant with the standard serum testing algorithms. Unfortunately, licensed confirmatory procedures are currently not available and are an impediment to the routine use of non-traditional specimens. Hopefully this issue will resolve itself in the future as these products become licensed.

The use of rapid (<15 min) assays to detect HIV antibody in the clinic-based setting have yet to be proven themselves. Conflicting data exist as to whether clients will wait for their results from these rapid tests. ASTPHLD restates the position that persons should not be informed of a positive result unless it was confirmed by a more specific test such as WB or IFA.

There are several companies working with health departments and CDC to refine home sample collection devices. These are NOT home testing kits, but devices in which a specimen will be collected at home, mailed to a reference lab, and the client will then call at a later date for their result. On-going surveys suggest that these collection devices are technically feasible. However, since counseling is an integral part of HIV testing, the actual benefits of these devices is unproven.

ISSUES FORUM WESTERN BLOT FALSE POSITIVE AND ISSUES OF TESTING IN THE ERA OF VACCINES

PANEL MODERATOR:

Michael Ascher, M.D., Chief, AIDS Support, VDRL, California Department of Health Services, Berkeley, California

PANEL MEMBERS:

J. Richard George, Ph.D., Research Microbiologist, Centers for Disease Control and Prevention, Atlanta, Georgia

Haynes W. Sheppard, Ph.D., Research Scientist, VRDL, California Department of Health Services, Berkeley, California

Keith Sayre, M.S., Product Manager, Ortho Diagnostics, Raritan, New Jersey

In the continuing evolution of screening tests for HIV capable of narrowing the "window period" and detecting the HIV-2 variant, problems with nonspecificity of the EIA assays have occurred. The false-positive samples arising from this situation are samples that come from uninfected individuals but which test positive on one or more screening assays and have a positive confirmatory test result. The Western blot patterns are incomplete suggesting seroconversion consisting of either envelope-only reactions at the regions of gp41, gp120 and gp160, or the coincidence of such envelope band(s) with the occurrence of a false positive gag reaction, typically at p24. These samples contain no other bands and they fail to progress over time to a more complete pattern of bands on Western blot. Some of these samples are also positive on IFA. A positive antigen test can be useful in resolving such samples. Recombinant and sythetic peptide EIA tests give variable reactivity on these samples. A negative result using either test on an apparent seroconverter should be a "red flag" for further studies.

These samples first began to be described with the 1990 enhancement of EIA tests and have increased further with the use of newer generation combi HIV 1 2 tests.

Current recommendations establish that failure to progress at six months is definitive for lack of HIV infection. However, in most cases, the resolution of such samples can be made by examining a followup sample for progression of band pattern at a one to three month interval.

It is therefore recommended that all samples having the appearance of a minimal seroconversion on blot (with no other bands) can be reported as positive but that the written result should include a note that such results can be nonspecific and that a followup sample is recommended to establish progression to a more complete pattern. The time limit for defining absence of infection should be stated.

Samples from those who have participated in HIV vaccine trials may give unusual patterns, resulting in erroneous interpretations. Studies to differentiate such specimens from true positives are in progress.

ROUND TABLE: INTERNATIONAL PERSPECTIVES

MODERATOR:

William J. Hausler, Jr., Ph.D., Director, University Hygienic Laboratory, University of Iowa.

PANEL MEMBERS:

Elizabeth M. Dax, M.D., National HIV Reference Laboratory, Australia

Ofelia Monzón, M.D., Consultant, ADS Research Group, Research Institute for Tropical Medicine, Manila, Philippines.

The fundamental purpose was to discuss ways in which the ASTPHLD could provide its assistance or presence in the international sphere of retrovirus testing.

Discussants made it very clear that the early consensus conferences did much to establish international recognition of standards of laboratory performance and reporting. Problems cited were inability to replicate USA laboratory environments, personnel, acquisition of reagents and specimen transport. In addition, many countries do not have sufficient regulations in force to prevent import and sale of reagents near or just beyond expiration date.

Countries outside the USA are not so much in need of training for relatively simple retrovirus laboratory diagnostic techniques as they are for assistance in guiding them to develop their own operational standards based on indigenous problems not encountered in the USA. The ASTPHLD was encouraged to become more active in assisting countries in the laboratory testing standardization process now that the WHO has significantly reduced its laboratory component.

The program committee is challenged to provide an international activities section within each Conference on Human Retrovirus Testing where laboratory scientists, manufacturers and program managers can meet and discuss issues of direct concern in human retrovirus testing in non-USA areas. The epidemic of HIV infection continues to expand and the ASTPHLD needs to maintain its public health laboratory leadership role.

ABSTRACTS

(Abstracts were reproduced in the conference program)

- 1 **Multisite Evaluation of the Murex SUDS® HIV-I Test for Detection of Antibody to Human Immunodeficiency Virus Type 1**, Richard C. Alexander, Dennis Ferrero, Bruce Fujikawa.
- 2 **HIV Study comparing the ability of serum, urine and saliva to Detect HIV seropositivity in known HIV-1 positive individuals**, M.A. Wilke, M.A. Baker, L.M. McIntosh, L.M. Killingsworth, L.R. Bernard.
- 3 **Does contact between Dried Blood Spots transfer HIV Seropositivity?** Carol J. Bell, Trudy L. Dobbs, and W. Harry Hannon.
- 4 **Comparative Performance of a Synthetic Peptide Assay as a Supplemental Test for HIV Antibody Detection**, S.B. Bennett, S. Fordan, S. Lampp, E.E. Buff, E.C. Hartwig, D. Frazier.
- 5 **Detection of HIV-1 Proviral DNA in Patient Samples Using a Novel Single-Temperature Amplification**, T.B. Ryder, E.R. Billyard, D.K. Cabanas, F. Garduno, T. Lawrence, K. Nunomura, G. Schneider, T. Smith, K. Ueding.
- 6 **A Microparticle Enzyme Immunoassay for the detection of antibodies to HIV-1 and HIV-2 on a Random Access Automated Analyzer**, W. Black, G. Hall-Steele, S. Stewart, S. Kramer, B. Sehgal, D. Daghfal
- 7 **Inter-shipment Reproducibility of HIV-1 Western Blot (WB) Results Reported in Five Paired Shipment Periods by Laboratories in a Model Performance Evaluation Program**, Sharon O. Blumer, James H. Handsfield, William O. Schalla.
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- 9 **Use of a Rapid HIV-1 Screening Test to improve client return rates**, R. Rockwell, C. Cossen, R. Alexander, D. Ferrero, B. Fujikawa.
- 10 **Evaluation of Laboratory Performance of T-Lymphocyte Immunophenotyping (TLI) in Support of HIV-1 Infected Patient Care and Management**, C.D. Cross, W.O. Schalla, R.N. Taylor, J.H. Handsfield.

- 11 **Sensitivity Comparison of an Antigen Conjugate EIA (Abbott List 3A77) with an Indirect EIA (Abbott List 3A11): Correlation with the PResence of Anti-p41 Antibody in HIV-1 Indeterminate Samples as Determined by a Recombinant Dot Blot Assay (Abbott Matrix HIV-1/HIV-2),** M.B. Peterson, K.M. Knigge, R.L. Falcon, C.K. Daluga, C.A. Skora, J.L. Gallarda, K.M. Knigge, B.L. Daanen.
- 12 **In-field Assay Specificity of Anti-HIV-1/HIV-2 EIAs in Australian Blood Banks,** Marisa Bendistinto, Thomas A. Vandebelt, Elizabeth Dax.
- 13 **Universal Donor Screening for HTLV in Australia: A review of testing results,** Elizabeth A. Dax, Colin Silvester, Marisa Bendistinto, Anna Karopoulos, Thanh Ha Huynh, Marina Karakaltsas, Fiona Rae, Susan J. Best, David S. Healey, Thomas A. Vandebelt, Jeff Clancy.
- 14 **HIV-1 Western Blot compared with Enzyme Immunoassay in HIV-1 Seroconversion,** Thanh Ha Huynh, David S. Healey, Colin Silvester, Elizabeth M. Dax.
- 15 **An Assessment of New York State's Experience as an HIV-1 Referral Testing Laboratory: Suggestions and Considerations,** C. Flood, M. Neal, J. Wethers.
- 16 **Blind Proficiency Studies for T-Lymphocyte Immunophenotyping,** D.P. Francis, K.M. Peddecord, A.S. Benenson, L.K. Hofherr, J. Rau, Q. Xie, D.B. Scharf, G.D. Cross, W.O. Schalla.
- 17 **Report Content of HIV-1 Antibody Testing Results,** A.S. Benenson, K.M. Peddecord, L.K. Hofherr, D.P. Francis, R.S. Garfein, J. Rau, Q. Xie, D.B. Scharf, R.N. Taylor, W.O. Schalla, R.E. Safrin, N.A. Dewan.
- 18 **Comparison of sensitivity of Two New Commercial Enzyme Immunoassays for the Detection of HTLV-1 and HTLV-11 Antibody,** Dana Gallo, Shideh Kashe, Marjorie Hoffman.
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- 20 **Delineation of an Immunodominant and highly HTLV specific epitope within HTLV-1 Transmembrane Glycoprotein,** Kenneth G. Hadlock, Chin-Joo Goh, Peggy A. Bradshaw, Susan Perkins, Rima Khabbaz, Jonathan Lo, Steven K.H. Fong.
- 21 **Possible False Positivity with HIV-1 envelope only reactivity on Western Blot identified through detection of plasma RNA,** Denis R. Henrard, Jack Phillips, Christine V. Sapan, Lynne Layug, Roger Dodd.
- 22 **Detection of HIV-2 Antibodies in Saliva,** Lindsay Hofman, Lebah Lugalia and Chyang Fang.
- 23 **Performance Evaluation of a Synthetic Peptide-Based Screening EIA for HTLV-I and II Antibodies,** Barbara Hosein, Alan Walfield, John Ye, Rosanne Boyle.

- 24 **Comparison of Licensed HIV 1/2 combination EIA's for early detection of HIV-1 Antibodies**, Pamela Markwardt-Elmer, Lisa Hughes, and Joan Pfister.
- 25 **Base Dissociation Assay (BDA) for Immune-Complex Dissociation (ICD) and Detection of HIV-1 p24 compared with three commercial ICD Kits**, J.M. Hyman, D.E. Lockwood, T.J. Holody, P. Youngbar.
- 26 **Performance of an immunoassay for simultaneous detection of antibodies to HTLV-I and HTLV-II**, Joan Johnson, Emerson Chan, Mark Buytendorp, Cheryl Motley, Eugene Robertson, John Stephens, Bruce Phelps.
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- 30 **HIV-1 ELISA System Enhancements to Improve specificity; Performance of OTC's Vironostika HIV-1 Microelisa System (VirHIV-1) (Cat. #59600 Series) in Dried Blood Spot (DBS) Specimen Populations**, Kay, J.W.D., Jones, G.R., Witt, D.
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- 35 **An Evaluation of an Indirect Immunofluorescence Assay (IFA) for confirmation of HIV-1 Antibody in Adult Sera and in Eluates of Dried Blood Spots**, Neal, M., Wethers, J.
- 36 **Evaluation of MicroTrak® II HIV-1/HIV-2 Recombinant EIA**, S. Phillips, T. Granade, J.R. George.
- 37 **Improved Detection of HIV Antigen Following Alkaline Dissociation of Immune Complexes**, M. Ramirez, N. Swack, S. Berberich, J. Stapleton.

- 38 **Comparison of Three Sets of Western Blot Interpretive Criteria: (Data from the National HIV Seroprevalence Surveys),** Martha A. Redus, Catherine L. Spruill, Marta Gwinn, Susan Davis, Charles Schable, J. R. George.
- 39 **HIV-1/HIV-2 Recombinant/Peptide EIA: The Next Generation,** C. Skora, B. Daanen, C. Daluga, B. Falcon, M.B. Peterson, J. Gallarda.
- 40 **Detection of HTLV-I and HTLV-II Antibodies by HTLV-I Assays: A Comparison of Eight Assays,** B.J. Weiblen, R.T. Schumacher, S.R. Delaney, V. Rieckenberg, S.L. Stramer, H. Kiyokawa.
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